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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/752,533	12/29/2000	Stephen M. Coutts	252312005704	1380
25226	7590	08/31/2006	EXAMINER	
MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018			LUKTON, DAVID	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 08/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/752,533

Applicant(s)

COUTTS ET AL.

Examiner

David Lukton

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 129 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Pursuant to the directives of the response filed 5/30/06, claims 157-168 have been added, and the following claims amended: 22, 32, 36, 51, 53, 54, 64, 75, 79, 106, 111, 119, 124, 143, 146 & 155. Claims 22, 23, 26, 32, 35, 36, 43, 45, 46, 51-54, 64-77, 79-82, 84, 86, 89, 99-111, 113-125, 128-144, 146-168 are now pending.

Claims 22, 23, 26, 32, 35, 36, 43, 45, 46, 51-54, 64-77, 79-82, 84, 86, 89, 99-111, 113-125, 128, 130-144, 146-168 are examined in this Office action; claim 129 remains withdrawn from consideration.

Applicants' arguments filed 5/30/06 have been considered and found persuasive in part. The "ODP" rejection over USP 5,552,391 is withdrawn in view of the terminal disclaimer. The §112, first paragraph (enablement) rejection of claims 38, 127 and 145 is rendered moot. The §112 second paragraph rejections are withdrawn. The §103 rejections of claims 22 and 54 are withdrawn as well.

. . . . .

The abbreviations "VPM", "BAM" and "PEG" are as defined previously.



Claims 22, 64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. USP 5,276,013.

In response to this ground of rejection, applicants have argued that the controlling question is the following: "...do the host of conjugates defined by claim 1 of the '013

patent as a whole render the chemically defined conjugates defined by claim 22 or 64 obvious...?”. This statement of the issue is repeated at the bottom of page 23 of the response. The examiner, however, disagrees that this is the controlling question in the instant case. The examiner’s argument would be that the controlling question (at least in this particular case) is whether or not there exists at least one embodiment within the scope of claim 1 of the ‘013 patent that falls within the scope of instant claim 22 or 64.

Applicants have also referred again to *In re Kaplan* (229 USPQ 678, 1986). As the examiner noted previously, claim 1 of USP ‘588 is drawn, in essence, to a process of making alkane polyols by hydrogenating carbon oxides, whereas claim 1 of USP ‘551 is a Jepson claim. Applicants have argued that “claim format is not relevant to an obviousness double patenting analysis”. The examiner disagrees. The issue here is the extent to which the situation that arose in the Kaplan case is relevant or controlling in the instant case. The examiner would agree that the Kaplan case is at least peripherally relevant; however, it is not controlling. Applicants have argued that the issue in the Kaplan case was simply that of a genus claim being used to reject a species claim. However, the issue was somewhat more complicated than that. As noted above, claim of USP ‘588 is drawn to a process a making a genus of compounds by using a genus of reaction conditions, whereas claim 1 of USP ‘551 is an improvement on the prior procedure which requires certain criteria be met, i.e., that the rate of formation of the polyol is greater than would have been obtained had tetraglyme been

used in the absence of sulfolane, or *vice versa*. Accordingly, Kaplan is not simply a genus/subgenus issue.

Applicants have also attempted to dismiss the relevance of *In re Baird* (29 USPQ2d 1550, 1994). Applicants have pointed out that Baird pertained to a §103 issue, rather than double patenting. The examiner also pointed this out preemptively. It may turn out, at some point in the future, that the Court will advocate a policy of barring examiners from looking to the specification to see what is encompassed when the issue is obviousness double patenting, but mandating that examiners look to the specification to see what is encompassed when the issue is obviousness. At the present time, however, it is not clear from the case law that the Court is advocating such seemingly contradictory positions. And to the extent that one can read a contradiction into the Court's various opinions, resolution of that conflict would appear to be called for.

Applicants have encapsulated the essence of the disagreement by arguing that examiners can only consider claims of an issued patent "in their entirety" and that they are barred from looking to the specification for specific embodiments contained within the claimed genus. The examiner maintains that examiners are not barred from pointing out, as a basis for their rejection, specific embodiments that are disclosed in the specification and which are encompassed by the claims (in the issued patent).

Claims 22, 64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. USP 6,060,056. Although the conflicting claims are not identical, they are not patentably distinct from each other.

As indicated previously, claim 64 is drawn to a (composition comprising a ) conjugate of a VPM and a BAM. Claim 1 of '056 is drawn to a conjugate of a VPM and a BAM, wherein the BAM must be an analog molecule of an immunogen. Although the scope of the compounds encompassed by BAM is more limited in the '056 patent than is the case here, there is still overlap between the respective genera. Applicants have stated that their arguments given in response to the ODP rejection over USP 5,276,013 apply here as well. The examiner does the same.



Claims 22, 64 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22 and 32 of U.S. Serial No. 09/753350. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Applicants have requested that this issue be deferred until the extent of allowable subject matter has been determined.



Claims 22, 64, 78 and 80 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 96 of U.S. Serial No. 10/867,874.

Applicants have requested that this issue be deferred until the extent of allowable subject matter has been determined.



The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22, 23, 26, 32, 35, 36, 43, 45, 46, 51-54, 64-77, 79-82, 84, 86, 89, 99-111, 113-125, 128, 130-144, 146-168 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Descriptive support is lacking for the claimed invention. One issue concerns the following phrase in claim 22:

“the valency of said VPM is provided by at least four but no more than 32 attachment sites located at termini of the VPM”

It is noted that, within the specification, there are a few examples of specific compounds

that fall within the scope of the claimed genus. However, neither one specie nor 20 species constitutes a description of a genus. It is also noted that the term “terminus” or “termini” occurs nine times in the specification. However, in none of these cases is the term used in reference to a genus, and certainly in no case is used in reference to a genus in which there are four attachment sites located at such termini.

In response to this ground of rejection, applicants have pointed to page 6, line 31+, wherein it is stated that, with regard to formula 2, integer variable  $n^{[2]}$  is within the range of 1-8 or within the range of 1-4. However, the issue is not simply that of integer variable  $n^{[2]}$ ; variable  $p^{[2]}$  must also be taken into account. Either way, there is no description of the range 4-32. Furthermore, even if it is true that there is a description of the range 4-32, this range would only apply to formula 2, wherein variable  $T^{[2]}$  is limited to one of a small number of possibilities (i.e., those on page 5, line 5+), and not to just any “attachment sites”. Similarly, in formula 2, variables  $L^{[2]}$  and  $J^{[2]}$  are limited (page 6, line 24+); not so in the instant claims.

Applicants have argued that any one of the features (taken by itself) of the claimed genus can be found in the specification. The examiner would argue that this is not necessarily true, but even if it is, the more important issue is that what applicants have done is to “pick and choose” limitations from a myriad of possibilities. This process of “picking and choosing”, as well as any subgenus resulting from this process, constitutes new matter.



Thus, in presenting the instant claims, applicants have expanded the scope of L<sup>[2]</sup>, J<sup>[2]</sup>, Z<sup>[2]</sup> and T<sup>[2]</sup>, created a new range for the product of p[2] and n[2], and combined the foregoing with limited a subgenus for G<sup>[2]</sup>.

Accordingly, one of skill would conclude that the claimed genus is not described in the specification.



THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON, PH.D.  
PRIMARY EXAMINER

**Continuation of Disposition of Claims:**

Claims pending in the application are 22,23,26,32,35,36,43,45,46,51-54,64-77,79-82,84,86,89,99-111,113-125,128-144 and 146-168.

**Continuation of Disposition of Claims:**

Claims rejected are 22,23,26,32,35,36,43,45,46,51-54,64-77,79-82,84,86,89,99-111,113-125,128,130-144 and 146-168.